Novel Double-Needle System That Can Prevent Intravascular Injection of Any Filler

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Summary: A new type of needle system combines 2 parts, an inner needle and an outer needle. The inner needle is used for filler injection and the outer needle acts as a guiding needle that can observe blood reflow when inserting into the vessel lumen during injection process. This new needle system can be used for all kinds of filler, providing real-time monitoring for physician and preventing intravascular injection of any filler. (Plast Reconstr Surg Glob Open 2017;5:e1496; doi: 10.1097/GOX.0000000000001496; Published online 25 September 2017.)

INTRODUCTION

Filler is widely used today for facial rejuvenation, but there are various serious adverse effects reported because of intravascular injection of filler. There are many methods to prevent intravascular injection, such as aspiration, using cannula, yet none are completely safe for all kinds of filler.1 This is due to the fact that the physician has no visual warning during the injection process. There are more than 100 cases of blindness caused by intravascular injection of filler reported in the literature.2 Based on current literature findings, intravascular injection has become an important issue with regard to patient safety. We present a novel double-needle system that can prevent intravascular injection and alert physicians during the injection process. The design can work well with all types of fillers.

We presented a new needle structure that can detect intravascular injection of filler by using the pressure difference between air pressure and intravascular blood pressure.3 However, there were technical difficulties in making a septum inside the needle lumen in mass production. Therefore, we build a new prototype needle system without the septum that can still prevent intravascular injection by observing blood reflow because of the pressure difference between air and intravascular blood pressure.

MECHANISM

The needle is composed of 2 parts: the inner needle and the outer needle. The inner needle is used for filler injection and the outer needle acts as a guiding needle that can observe blood reflow when inserting into the vessel lumen during injection process. A small hole in the wall of the outer needle acts as a passage for air and balances air pressure. The mechanism of the whole needle structure simulates the process of phlebotomy (Fig. 1; see figure, Supplemental Digital Content 1, which displays (a) the inner needle component fully detached from the outer needle component and (b) the assembled double-needle system in a closer view, note the relationship between inner and outer needle tip, http://links.lww.com/PRSGO/A531). During phlebotomy, when the needle tip taps into a vessel lumen, we can see blood in the anterior needle chamber, alerting the physician. In our novel needle structure, the outer needle compartment is designed similarly. When the outer needle tip is inside the vessel lumen, the physician can observe blood in the outer compartment. If the needle tip is not in the vessel lumen, there will be no reflow of blood. By direct observation, we can prevent intravascular injections of filler (see video, Supplemental Digital Content 2, which displays the structure of the needle system and how it works in practice, http://links.lww.com/PRSGO/A532).

METHODS

We used a Becton, Dickinson and Company 1 ml syringe with Luer-Lok tip and 27-gauge needle for the inner needle. Radiesse was used as filler and was transferred into each inner needle chamber, then 0.1 cc of the filler was injected into the veins or arteries of the tail of the rats by an experienced technician who is familiar with the anatomy of the rats. This is the same injection procedure that we usually do in animal experiment. Needle was inserted into

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the veins and arteries of the tail of rats. The time it took to observe the flow of blood into the outside needle chamber was recorded. If there were no signs of blood reflow, injection of the filler into the vessels was performed 10 seconds later.

Total samples of 20 rats were used and were separated into 2 groups of 10. In each group, needle was inserted into veins of 5 rats and another 5 into arteries. We record the time we need to observe blood reflow in the outer needle chamber. If no blood reflows, we inject filler into vessels after 10s later.

In group 1, we used 1 cc syringe without outer needle chamber system, and the filler was injected into the arteries and veins. We record the time needed to observe blood reflow in the outer needle chamber. If no blood reflows, we inject filler into vessels after 10s later.

In group 2, outside needle chamber system was harnessed onto the 1 cc syringe, which created an inner and outer chambers. We record the time needed to observe blood reflow, and injection of fillers into the vessels is not performed if we observe blood reflow (Table 1).

We can clearly see the blood reflow during injection in group 2 by using our outer needle system. There is no blood reflow without using the outer needle system which is seen in group 1 (see figure, Supplemental Digital Content 3, which displays an (a) injection without outer needle system in artery: No blood reflow is observed. (b) Injection with outer needle system in artery: Clear blood reflow is observed. (c) Injection without outer needle system in vein: No blood reflow is observed. (d) Injection with outer needle system in vein: Clear blood reflow is observed, http://links.lww.com/PRSGO/A533). Therefore, there is a clear difference between using the novel system or not when we are targeting vessel injection.

DISCUSSION

There were many side effects of filler reported, but the most devastating one was intravascular injection. There were more than 100 blinded cases reported after filler injection. Therefore, it is crucial for the physician to have a convenient and safe tool to prevent intravascular injection. Using the aspiration method and blunt needle is advocated by some doctors. But aspiration is not 100% safe when using smaller gauge needle. Using a blunt cannula is safer but not suitable in every case and cannot provide a very precise injection point if we wanted to place filler just above the bone or in different plane of our face.

The advantage of this novel structure is real-time monitoring of filler injection. And any intravascular injection can be monitored by appearance of blood in the needle chamber. Any filler can work well in this design. If during an injection procedure blood comes out, we do not need to open a new clean device for continuing the injection; we move the inner needle to advance blood out. Then the outer needle can still have the function of the observation of the reflow. The physician can discriminate the position of needle tip in a safe area or not. This structure can prevent intravascular injection and provide a much safer injection process for the patients.
However, there are some disadvantages of the present structure. We build this prototype with a 21G outer needle with a 27G inner needle. During the filler injection, smaller diameter of needle less than 25G was usually used. Hence, 21G is too large for filler injection. However, to solve this problem, we must understand that the size of the needle is based on the wall thickness. For example, we know that currently on the market the finest needle wall is about 0.0508 mm in thickness, and the inner diameter of a 27g needle is 0.210 mm. If we use the 27g needle as our base model plus 4 layers of 0.0508 mm thin wall, the outer diameter of outer needle can be a little bigger than 0.4132 mm, which is less than the diameter of 26g needle, yet to achieve this caliber of the needle, this type of needle must be custom made.

The other issue that needs to be addressed related to the practicality of this device is the needle length due to its impact on the back flash noted. Our outer needle is 13 mm long, which is the same length as the 27g needle that is commonly used in filler injection. The system works well in vein and artery because there is pressure difference in the artery and veins; the blood will go from high pressure area to low pressure area. The mechanism is the same as in phlebotomy. When we take blood sample, we usually use 23G needle with a needle length of 25 mm, and blood reflow is easily seen in this caliber of needle. Besides, the most devastating side effects come from intraarterial injection, where the blood pressure is high enough to generate blood reflow in needle length less than 5 cm.

Nonetheless, further investigation and study are still necessary for the system and other modality to reduce the side effect of filler injection due to intravascular injection.

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**REFERENCES**